

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) PAT051722-US-PCT									
		Application Number 10/564,474	Filed (Int'l.) July 15, 2004								
		First Named Inventor Roberto OLIVIERI et al.									
		Art Unit 1645	Examiner L. J. Tongue								
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <table> <tr> <td><input type="checkbox"/> applicant /inventor.</td> <td>/Otis Littlefield/ Signature</td> </tr> <tr> <td><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</td> <td>Otis B. Littlefield Typed or printed name</td> </tr> <tr> <td><input type="checkbox"/> attorney or agent of record. Registration number _____</td> <td>415.268.6846</td> </tr> <tr> <td><input checked="" type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. <u>48,751</u></td> <td>Telephone number September 23, 2010 Date</td> </tr> </table> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p> <p><input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.</p>				<input type="checkbox"/> applicant /inventor.	/Otis Littlefield/ Signature	<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)	Otis B. Littlefield Typed or printed name	<input type="checkbox"/> attorney or agent of record. Registration number _____	415.268.6846	<input checked="" type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. <u>48,751</u>	Telephone number September 23, 2010 Date
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Novartis Docket No. PAT051722-US-PCT
Mofo Docket No.: 223002110300
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Roberto OLIVIERI et al.

Application No.: 10/564,474

Confirmation No.: 9877

Filed: (Intl.) July 15, 2004

Art Unit: 1645

For: ULTRAFILTRATION FOR PREPARING
OUTER MEMBRANE VESICLES

Examiner: L. J. Tongue

ARGUMENTS ACCOMPANYING PRE-APPEAL BRIEF REQUEST FOR REVIEW

MS AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INTRODUCTORY COMMENTS

The following arguments are presented in support of the Pre-appeal Brief Request for Review being filed concurrently with a Notice of Appeal.

Remarks/Arguments begin on page 2 of this paper.

REMARKS

Claims 1-23 are pending. Claims 8 and 16-23 are withdrawn.

I. Claim Rejections Under 35 USC §102 – Zollinger

Claims 1-7, 9-12, 14 and 15 have been rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Zollinger *et al.* (U.S. Patent 6,558,677 B2).

Applicants respectfully traverse the rejection and its supporting remarks. Zollinger *et al.* fail to teach the claimed “step of ultrafiltration of a crude OMV preparation *containing bacterial DNA*”. The Examiner has asserted that Zollinger *et al.* teach in Col. 16, lines 1-16, splitting the cell extract into two parts prior to ultracentrifugation. The Examiner then points to Col. 16, lines 30-33, as teaching ultrafiltration of one of the two parts of the cell extract. However, the Examiner leaped over the intervening step Zollinger *et al.* teach in Col. 16, lines 17-29. Before Zollinger *et al.* subjected the cell extract to ultrafiltration, Zollinger *et al.* added DEAE cellulose to the cell extract. Zollinger *et al.* expressly state “After this step the extract was found to be essentially free of nucleic acid.” Thus, Zollinger *et al.* did not apply a step of ultrafiltration of a crude OMV preparation containing bacterial DNA because they removed the DNA before ultracentrifuging.

Applicants therefore respectfully request that the Examiner withdraw the rejection of claims 1-7, 9-12, 14 and 15.

II. Claim Rejections Under 35 USC §102 – Granoff

Claims 1-7 and 9-13 have been rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Granoff *et al.* (U.S. 2006/0029621).

Applicants respectfully traverse the rejection and its supporting remarks. In order to anticipate a claimed invention, a reference must expressly or inherently teach all of the claimed elements.

A. *Granoff et al. do not Expressly Teach Ultrafiltration of a Crude OMV Preparation Containing Bacterial DNA*

Granoff *et al.* do not expressly teach the claimed “step of *ultrafiltration* of a crude OMV preparation *containing bacterial DNA*”. The Examiner has asserted that the single sentence in paragraph [0085] anticipates the claimed invention. However, nowhere in the single sentence pointed to by the Examiner do Granoff *et al.* teach that a crude OMV preparation *containing bacterial DNA* is subject to ultrafiltration. The sentence does not mention how to deal with bacterial DNA at all and only references filtration (not ultrafiltration specifically) among a number of techniques that may generally be used, which is a broad category of techniques only one of which is filtration. Filtration includes sterile filtration with 0.22 µm filters, which is clearly not ultrafiltration. There is no detail about how to actually implement any of these broad categories of techniques such as whether preliminary processing would be required before use of the technique (*e.g.*, removal of bacterial DNA and other cellular debris). Thus, Granoff *et al.* does not *expressly* anticipate the pending claims.

B. *Granoff et al. do not Inherently Teach Ultrafiltration of a Crude OMV Preparation Containing Bacterial DNA*

Since Granoff *et al.* does not expressly teach the above elements, the only way paragraph [0085] of Granoff *et al.* could anticipate the pending claims is if this single sentence *inherently* teaches *ultrafiltration* of a crude OMV preparation *containing bacterial DNA*. MPEP 2112(IV) sets out the requirements for inherent anticipation as:

The fact that a certain result or characteristic *may* occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is *necessarily present* in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, *may not be established by probabilities or*

possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.”” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) ...

Thus, even if one of skill in the art were so bold as to attempt to purify OMVs based solely upon the single sentence of Granoff *et al.*, it is not enough that it *may* lead to *ultrafiltration* of a crude OMV preparation *containing bacterial DNA*. One of skill in the art practicing this single sentence must *necessarily* perform “a step of ultrafiltration of a crude OMV preparation containing bacterial DNA prior to any ultracentrifugation or sterilisation steps.” The burden to establish inherency is clearly on the Examiner. The Examiner cannot merely assert that inherency is found absent evidence to the contrary. Thus, unless the Examiner can provide evidence or sound reasoning that one of skill in the art would follow this single sentence of Granoff *et al.* and necessarily perform *ultrafiltration* of a crude OMV preparation *containing bacterial DNA*, the Examiner has not established that Granoff *et al.* inherently anticipates the claimed invention.

Granoff *et al.* do not expressly teach all of the claimed elements and do not inherently teach all of the claimed elements. Therefore Granoff *et al.* do not anticipate the present claims.

Applicants therefore respectfully request that the Examiner withdraw the rejection of claims 1-7 and 9-13.

III. Claim Rejections Under 35 USC §102 – Berthet

Claims 1-7 and 9-15 have been rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Berthet *et al.* (U.S. 2006/0204520 A1) is maintained for the reasons set forth in the previous office action.

Applicants respectfully traverse the rejection and its supporting remarks. The Examiner has cited to paragraphs [0037] and [0058] of Berthet *et al.* and asserted that “sterile filtration” as disclosed by Berthet *et al.* anticipates the claimed invention. The independent claim however requires “ultrafiltration … *prior* to any ultracentrifugation or *sterilisation* steps.” Even if the sterile filtration taught by Berthet *et al.* was “ultrafiltration” as claimed, the filtering and sterilization are happening at the same step and therefore is not within the scope of the claims.

Applicants therefore respectfully request that the Examiner withdraw the rejection of claims 1-7 and 9-13.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **Docket No. 223002110300**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: September 23, 2010

Respectfully submitted,

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